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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/424,519	03/03/2000	JAMES B. MITCHELL	175931	8084

7590 09/18/2002

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EXAMINER
KWON, BRIAN YONG S

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 09/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/424,519	Applicant(s) MITCHELL ET AL.	
	Examiner Brian S Kwon	Art Unit 1614	

-- The MAILING DATE of this communication appears on th cover sheet with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 June 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 22-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 22-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. In view of the Appeal's Brief filed on June 24, 2002, PROSECUTION IS HEREBY REOPENED. New ground of rejection is set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) request reinstatement of the appeal.

If reinstatement of the appeal is requested, such request must be accompanied by a supplemental appeal brief, but no new amendments, affidavits (37 CFR 1.130, 1.131 or 1.132) or other evidence are permitted. See 37 CFR 1.193(b)(2).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-3 are rejected under 35 USC 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The present claims are drawn to a method for treating or preventing cancer in an animal, comprising administering a sufficient amount of said nitroxide or prodrug thereof, namely

Tempol, to an animal at risk for developing cancer or having a cancer, wherein said cancer is susceptible to prevention or treatment by said nitroxide or prodrug thereof. The instant invention alleges that claimed methods are only limited to the prophylactic or therapeutic treatment of those cancers susceptible to prevention or treatment by nitroxides or prodrugs thereof (page 2, lines 13-14 of Response filed May 7, 2001). However, the specification disclosure clearly does not provide an adequate representation regarding which types of cancers are susceptible to nitroxide or prodrug thereof.

At the time of the invention was made, it was not known that nitroxide, namely Tempol, is effective in preventing or treating cancers other than skin cancer.

Although the instant specification discloses the efficacy of a nitroxide, namely Tempol, in decreasing the incidence of cancer and in delaying the onset of tumor related to p53 tumor suppressor gene mutation (Examples 1-2), none of the Examples do not clearly point out which types of cancers are responsive to the treatment of nitroxide or which types of cancers originate from a defect of the p53 gene. Furthermore, the instant specification fails to provide an adequate representation regarding which types of cancers are responsive to the treatment of nitroxide or prodrug thereof other than probable spleen cancer described in Examples (page 15, lines 30-31 and page 16, lines 21-22).

With the exception of skin cancer and probable spleen cancer, the skill artisan cannot envision the method of preventing or treating other cancers that are susceptible to the prevention or treatment by said nitroxide or prodrug thereof. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of the treatment.

Applicants claim for the prophylactic or therapeutic treatment of those cancers susceptible to prevention or treatment by nitroxides or prodrugs thereof does not meet the written description provision of 35 USC 112, first paragraph. The specification provides insufficient written description to support which types of cancers are susceptible to the treamtnet of nitrooxides or prodrug other than skin cancer and probable spleen cancer.

See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966(1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989)* ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.") Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966.*

3. Claims 22, 24 and 26 are rejected under 35 USC 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification discloses that "the method of the present invention comprises administering to an animal, preferably a mammal, more preferably a human, at risk for developing a cancer or having a cancer (e.g., a genetic defect or a proclivity for a genetic defect, such as an induced or inherited genetic defect, that promotes or causes cancer), a nitroxide or a prodrug thereof in an amount sufficient to prevent or treat said cancer, respectively, wherein said cancer is susceptible to prevention or treatment with said nitroxide or said prodrug thereof" (page 7, lines 9-18). The specification also discloses examples of a cancer regulatory gene or a tumor suppressor gene such a gene include ABEL, BCL2 and p53 gene which up-regulates or down-regulates a gene that causes cancer.

The claimed invention appears to be based on applicants discovery of using nitroxide, namely Tempol, in delaying the onset of tumor (probable spleen tumor) in p53 tumor suppressor gene deficient mice study, so called genetic "knock-out" models (Example 1). While the specification disclosure regarding the use of nitroxide in treating cancer related p53 tumor suppressor gene mutation meets the written description, applicants claim for the treatment of cancer related to the genetic defect of entire cancer regulatory genes or tumor suppressor genes does not meet the written description provision of 35 USC 112, first paragraph. The instant specification clearly do not provide adequate representation regarding what types of cancer regulatory genes or tumor suppressor genes are involved in cancers that are suceptible to the

treatment of nitroxides other than p53 gene. Furthermore, the specification fails to provide adequate representation to ascertain that p53 "knock-out" mice model could be a representative model for the entire genus of cancer regulatory gene or tumor suppressor gene. The specification provides insufficient written description to support the genus encompassed by the claim.

Vas-Cath Inc. Mahurkar, 19 USPQ2d 1111, makes clear the "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116).

With the exception of the p53 tumor suppressor gene, the skilled artisan cannot envision which types of cancer regulatory gene or tumor suppressor gene would be related to nitroxide-susceptible cancer, and subsequently subjected to the treatment of nitroxide or prodrug. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for the treatment.

See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

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...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966(1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989)* ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.") Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966.*

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

4. Claims 1-3 and 22-27 are rejected under 35 U.S.C. 102(e) as being anticipated by Bernstein (US 5840734).

Bernstein teaches the use of Tempol for preventing skin cancer by blocking UVR (column 2, lines 51-56 and claims 1 and 4). Although Bernstein is silent regarding "said cancer is due to a genetic defect of a cancer regulatory gene or a tumor suppressor gene", namely p53 gene, such characteristic or property must be inherently presented in the cancer susceptible to the prophylactic treatment of nitroxide. Therefore, the reference clearly anticipates the claimed invention.

5. Claim 1-2 are rejected under 35 U.S.C. 102(e) as being anticipated by Wang et al. (Anti-Cancer Drug Design, 1993, 8, 193-202).

Wang teaches the use of nitroxide compound such as GP-11 for inhibiting the growth of tumors (page 196-197).

Conclusion

6. No Claim is allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (703) 308-5377. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax number for this Group is (703) 308-4556.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

Brian Kwon

ZOHREH FAY
PRIMARY EXAMINER
GROUP 1600